

Notice of Allowability**Application No.**

09/423,715

Examiner

Lauren Q Wells

Applicant(s)

PASSMORE ET AL.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed 3/10/04.
2. ☒ The allowed claim(s) is/are 1-9, 12-19, 23, 25-27, 29-32, 34-37 (renumbered as claims 1-29).
3. ☒ The drawings filed on 11/12/99 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Claims 1-9, 11-20, 25-32 and 34-37 are pending. The Amendment filed 3/10/04, cancelled claim 33, and amended claims 1, 13, 14, 16, 17, 23, 31, 32, 35 36 and 37.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jay Maioli on 6/21/04.

The application has been amended as follows:

1) In claim 1, delete the last paragraph, i.e., the text of "wherein one of the first or the second pharmacologically active agent. . .or choline salicylate", **AND** delete the phrase ", and" in line 21.

2) Following the phrase "at least one compatible emulsifying agent," in claim 1, insert the following,

"wherein the first pharmacologically active agent is selected from the group consisting of chlorocresol, chlorbutanol, methyl nicotinate, triprolidine, promethazine, trimeprazine, sulфирam, oxybutynin, testosterone enanthate, and choline salicylate,

wherein the second pharmacologically active agent is selected from the group consisting of chlorocresol, trimeprazine, choline salicylate, methyl nicotinate, ibuprofen, ketoprofen, fenoprofen, flurbiprofen, etodolac, fentanyl, econazole, ketoconazole, mupirocin, chlorbutanol,

clindamycin, iodine, oxybutynin, tetramisole, triprolidine, promethazine, and propranolol, in which the at least two pharmacologically active agents are structurally and/or pharmacologically diverse,”.

1) In claim 23, delete the following (lines 24-31), “and wherein one of the first or the second pharmacologically active agent is triclosan. . .or choline salicylate,”.

2) Following the phrase “and at least one compatible emulsifying agent” in claim 23 (line 18), insert the following,

“wherein the first pharmacologically active agent is selected from the group consisting of triclosan, chlorocresol, chlorbutanol, methyl nicotinate, triprolidine, promethazine, trimeprazine, sulfiram, oxybutynin, testosterone enanthate, and choline salicylate,

wherein the second pharmacologically active agent is selected from the group consisting of triclosan, chlorocresol, capsaicin, trimeprazine, choline salicylate, methyl nicotinate, ibuprofen, ketoprofen, fenoprofen, flurbiprofen, etodolac, fentanyl, econazole, ketoconazole, mupirocin, chlorbutanol, clindamycin, iodine, oxybutynin, tetramisole, triprolidine, promethazine, and propranolol, in which the at least two pharmacologically active agents are structurally and/or pharmacologically diverse, and”.

3) Cancel claims 11, 20, 28.

4) Under the title on page 1 of the specification, insert the following, “This Application is a national stage entry of PCT/IE98/00036.”

5) On page 10, line 4, following the paragraph, “known in the art. . .suitable viscosity builders.”, please insert the following (see next page).

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

Claims 1-9, 12-19, 23, 25-27, 29-32, 34-37 are allowable over the prior art, as the prior art neither anticipates nor renders obvious the instant composition.

The closest prior art is US 5,854,246, which teaches oil-in-water emulsions containing ketoconazole, and other active ingredients such as chlorocresol. However, the reference fails to teach the active ingredients in the discontinuous phase (oil) and fails to teach a eutectic mixture. In fact, aside from not teaching eutectic mixtures, both the ketoconazole and the chlorocresol of the reference are dissolved in the aqueous phase and not the oily discontinuous phase. Furthermore, the process conditions of the reference do not permit direct contact between preservatives, i.e., chlorocresol, and ketoconazole, and, without that direct contact, a eutectic mixture of ketoconazole and a preservative will not occur.

The Amendment filed 3/10/04, is sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

The Examiner's Amendment in combination with the Arguments filed 3/10/04, is sufficient to overcome the 35USC 103 rejection in the previous Office Action.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**